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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,421	07/28/2005	Moise Azria	PA/4-32604A	1852

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KHANNA, HEMANT	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/523,421	AZRIA ET AL.	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) *1-3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10, 12-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/01/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of claims 7-10, and 12-13 that belong to Group I in the reply filed on November 03, 2006 is acknowledged. The traversal is on the ground(s) that while the inventions of Group I and Group II are distinct, because the European Patent Office did not allege a negative finding with respect to lack of unity of invention, the Applicants allege that the inventions reflect a common inventive concept.

The applicant's arguments are not found persuasive. The applicant has rightfully admitted that the inventions of Group I and Group II are distinct. Further, the Applicant has not argued the invalidity of the Bay et al reference cited in the Examiner's Office action filed May 05, 2006, which anticipates the special technical feature of a pharmaceutical composition comprising an oral delivery agent in combination with calcitonin. Neither has the Applicant identified the "special technical feature" which they allege is not anticipated. Additionally, the applicant is reminded that the International phase of the instant application did not cite the Bay et al reference, hence its importance in anticipating the special technical feature was not a consideration at the time of filing of the International phase.

The restriction between Groups I and II is maintained. Group I is drawn to method claims and the restriction is appropriate for the reasons set forth in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 7-10, 12-13 are pending. Claims 1-3 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-9, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7, and 12 recite the phrase "about 10 to about 250:1 by weight". Claim 8 recites the phrase "about 10 to about 200:1 by weight". Claim 9 recites the phrase "about 25 to about 100:1 by weight". The phrases recited by the above-mentioned claims are indefinite, because it is not clear how the phrases differentiate the composition ratios with respect to one another in view of the specifications definition of "about" as being a range falling within upto 10% below and above, and in the absence of any difference in the alleged end-points that result from the administration of the composition.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7-9, 12-13, rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg M. et al (WO 00/59480, as cited in the IDS filed February 01, 2005).

The instant claims are drawn to an oral pharmaceutical composition comprising an oral delivery agent and calcitonin combined in a range of ratios and kits comprising thereof.

With respect to claims 7-9, Goldberg M. et al disclose dosage forms of salmon calcitonin in composition with sodium salts (page 15) of the oral delivery agent, namely the delivery agent 1 (N-(5-chlorosalicyloyl)-8-aminocaprylic acid, 5-CNAC; page 5)) to deliver agents not ordinarily orally deliverable (lines 22-25, page 11). The dosage forms include amounts of material lyophilized in presence of a pharmaceutically acceptable buffer (page 16) to yield a capsule, tablet or powder, which is mixed with water and administered (lines 15-20, page 10) to rats. Goldberg M et al also that is known in the

art to vary doses and further disclose varying the doses of salmon calcitonin ranging from 100 μg to 360 mg (line 10, page 32) as well as varying the doses of the oral delivery agent ranging from 50 mg to 4.5 g (Table 2, page 21; line 14, page 32).

Goldberg M et al do not disclose kits comprising the combined composition of an oral delivery agent, 5-CNAC with salmon calcitonin.

In view of the teachings of Goldberg M et al it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the ratios of the two ingredients for the known and expected result of providing a means recognized in the art for maintaining bioavailability with change in body weight and with change in the type of solid dosage form.

With respect to claims 12-13, a kit comprising the pharmaceutical composition of the salmon calcitonin and 5-CNAC would have been merely an obvious matter of packaging the composition in kit form because kits are routinely used in the pharmaceutical arts for the purposes of storage, transportation, measurement and administration.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 7-9, 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Bay et al (US 2002/0065255).

The instant claims are drawn to an oral pharmaceutical composition comprising an oral delivery agent and calcitonin combined in a range of ratios and kits comprising thereof.

Bay et al teach hydrates, solvates, and disodium salts of delivery agents N-(5-chlorosalicyloyl)-8-aminocaprylic acid (5-CNAC), N-(10-[2-hydroxybenzoyl]aminodecanoic acid (SNAD), N-(8-[2-hydroxybenzoyl]amino) caprylic acid (SNAC) and compositions comprising the above-mentioned delivery agents in combination with salmon calcitonin (abstract; paragraph 0038; Example 19) for oral delivery in the form of capsules, tablets and particles, wherein the composition is administered to humans in the weight ratio range of oral delivery agent to the salmon calcitonin from about 100:1 to 500:1 (paragraph 38), thus meeting all the limitations of claims 7-9. With respect to the instant claims 12-13, the composition of Bay et al is deemed to anticipate the instant kit claims, whose only recited element is the composition of the delivery agent and salmon calcitonin. Also note that while claim 13 recites the use of the pharmaceutical composition to be taken prior to the consumption of food, this functional limitation of the claimed composition does not further distinguish the claimed kit structurally. Hence it should be noted that the above-mentioned functional recitation, or the intended use of the composition or kit is not given patentable weight. Hence sufficient evidence of similarity is deemed to be present between the composition of Bay et al and the Applicant's kit to shift the burden to the Applicant to

provide evidence that the claimed kit is unobviously different than the composition of Bay et al.

7. Claims 7-10, 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Ault et al (WO 02/45754).

The instant claims are drawn to an oral pharmaceutical composition comprising an oral delivery agent, calcitonin and crospovidone/povidone. Further the instant claims recite the combination of the delivery agent and calcitonin in a range of ratios and kits comprising thereof.

Ault et al teach solid pharmaceutical compositions of disodium salts (fourth paragraph, page 6) of the delivery agents N-(5-chlorosalicyloyl)-8-aminocaprylic acid (5-CNAC), N-(10-[2-hydroxybenzoyl]aminodecanoic acid (SNAD), N-(8-[2-hydroxybenzoyl]amino) caprylic acid (SNAC) in combination with salmon calcitonin (third paragraph, page 7; Example A, page 9) and crospovidone or povidone (claim 1, first paragraph, page 5) for oral delivery in the form of capsules, tablets and particles (first paragraph, page 8), wherein the composition is administered to Rhesus monkeys in the weight percent range of the salmon calcitonin from about 0.05 to 70 percent and in the range of the oral delivery agent from about 2.5 % to 50 % (last paragraph, page 4; last paragraph, page 7) thus meeting all the limitations of claims 7-10. With respect to the instant claims 12-13, the composition of Ault et al is deemed to anticipate the instant kit claims, whose only recited element is the composition of the delivery agent and

salmon calcitonin. Also note that while claim 13 recites the use of the pharmaceutical composition to be taken prior to the consumption of food, this functional limitation of the claimed composition does not further distinguish the claimed kit structurally. Hence it should be noted that the above-mentioned functional recitation, or the intended use of the composition or kit is not given patentable weight. Hence sufficient evidence of similarity is deemed to be present between the composition of Ault et al and the Applicant's kit to shift the burden to the Applicant to provide evidence that the claimed kit is unobviously different than the composition of Ault et al.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 7-9, and 12-13 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-20 of copending Application No. 10/615213 in view of Goldberg M. et al (WO 00/59480).

Claims 1-20 of co-pending Application No. 10/615213 teach a composition comprising a disodium salt, solvate of a genus of oral delivery agents comprising 5-CNAC, in presence of a genus of active agents comprising calcitonin, wherein the disodium salt of the delivery agent is atleast 90% by weight of the composition.

Goldberg M. et al teach pharmaceutical compositions in the form of an oral dosage comprising salmon calcitonin and 5-CNAC as the oral delivery agent. Further, Goldberg M. et al also teach that is known in the art to vary doses and further discloses varying the doses of salmon calcitonin ranging from 100 μg to 360 mg (line 10, page 32) as well as varying the doses of the oral delivery agent ranging from 50 mg to 4.5 g (Table 2, page 21; line 14, page 32).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant composition of a salmon calcitonin in presence of 5-CNAC, is prima facie obvious over a composition comprising a genus of disodium salts of delivery agents and a genus of active agents comprising calcitonin in view of the teachings of Goldberg M. et al who suggest the specific combination of salmon calcitonin with oral delivery agents, such as 5-CNAC as art recognized for increasing the bioavailability of bioactive agents.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide a pharmaceutical composition with the claims

drawn to a oral delivery agent and an active agent as claimed in the copending Application No. 10/615213.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 10 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,049,283.

Claims1-3 of U.S. Patent No. 7,049,283 teach an oral pharmaceutical composition comprising 5-CNAC, salmon calcitonin, crospovidone or povidone and other optional ingredients in a range of ratios.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The provision of an oral composition comprising a delivery agent, namely 5-CNAC in presence of 0.1-2.5 mg of salmon calcitonin and crospovidone or povidone wherein the delivery agent and calcitonin are present in a range of ratios, is prima facie obvious over a pharmaceutical composition comprising the same ingredients wherein the relative amounts of each including the crospovidone or povidone is stipulated.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to vary the ratios of the ingredients to attain the known and expected result of providing a means recognized in the art to optimize the delivery of active ingredients via solid dosage forms.

Conclusion

11. No claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hemant Khanna Ph.D.
November 17, 2006

B. DELL CHISM
PRIMARY EXAMINER